

# Regulatory and Safety Evaluation Specialty Section Newsletter

Society of Toxicology

## President's Message | Winter 2020

Dear Colleagues,

I hope that everyone is staying safe and healthy in the midst of all of the uncertainty that we are experiencing. I am sorry that we did not have the opportunity to meet face-to-face at the Annual Meeting. We missed out on so much that we look forward to each year--honoring our award winners, presenting our work, an excellent scientific program, and catching up with colleagues. We will likely see many changes in the coming months, but I am trying, as I hope all of you are, to be flexible and stay positive.



As we did not have the opportunity to hold our RSESS reception at the Annual Meeting, I would like to use this newsletter as a small way of honoring our award winners and celebrate their accomplishments as well as make a few announcements about upcoming events. Many congratulations to our award winners for your outstanding work!

We would also like to welcome our incoming officers to the RSESS Executive Committee (Kristina Chadwick—VP-Elect and Angelique Braen—Councilor). We are excited to have them join our leadership team!

Many thanks to Norman Kim (outgoing Secretary/Treasurer) and Marie Fortin (Immediate Past President) for all of their

contributions and service to RSESS. We will miss you!

As many of you have probably heard, SOT will be presenting various sessions of the scientific program (symposia and CE courses) through webinars, so please watch your email for the dates and times of these sessions.

In addition to the awards that RSESS currently has, we are pleased to announce the creation of a new award, which is the "Outstanding Contribution to Regulatory and Safety Evaluation Award". This award will be conferred at the 2021 Annual Meeting in Orlando, FL. Please watch your email for further information and how to nominate a colleague!

We will also be organizing some virtual mentoring events over the course of the next several months. More specific details related to the planning of these events can be found within the newsletter.

As always, we welcome membership participation in RSESS activities! Please contact any of the members of our Executive Committee with your thoughts, suggestions, or recommendations (contact information for the members of our EC are listed in the newsletter).

Cheers!

Anne E. Loccisano, PhD, DABT  
RSESS 2019-2020

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**Calling All Volunteers!****NEWSLETTER COMMITTEE**

- Now seeking editors and article contributors!
- Please indicate interest to Lauren Walker  
([Lauren.M.Walker@Rutgers.edu](mailto:Lauren.M.Walker@Rutgers.edu)).

**PROGRAM REVIEW COMMITTEE**

- Now seeking volunteers to review annual SOT Session Proposals for the 2021 Annual Meeting!
- Interested individuals should contact Amy Roe  
([roe.al@pg.com](mailto:roe.al@pg.com)).

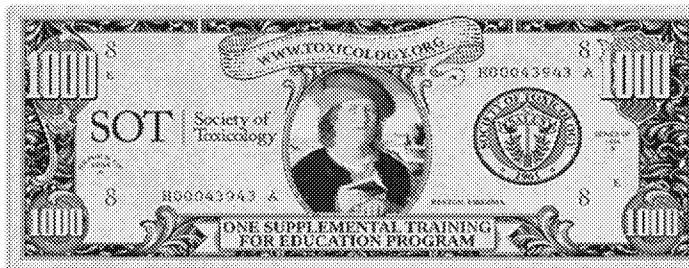
**ATTENTION TRAINEES (and mentors)!****Supplemental Training for Education Program (STEP)**

Next Deadline: May 1, 2020

Doctoral students are encouraged to apply with a strong application that proposes participation in a workshop or event that enables professional or scientific training needed to achieve career goals, but that is outside the scope of their graduate program.

For more info:

<http://www.toxicology.org/education/st/step.asp>

**New Experiences in Toxicology (NEXT) Program**

Next Deadline: May 1, 2020

Outstanding postdoctoral trainees are encouraged to apply to the NEXT program. The NEXT award covers costs associated with additional training related to toxicology that will broaden a postdoc's expertise and prepare them for the competitive job market. Applicants will identify professional development workshops, short courses, or activities that would provide training outside of their academic, governmental, or industrial postdoc.

For more info:

[www.toxicology.org/awards/sot/awards.aspx?AwardID=290](http://www.toxicology.org/awards/sot/awards.aspx?AwardID=290)

**Welcome to our incoming EC officers!****Kristina D. Chadwick, Ph.D., DABT, Vice President-Elect**

Kristina D. Chadwick recently transitioned to Global Regulatory Affairs and was previously a Director and Therapy Area Head for Fibrotic and Metabolic Diseases in Drug Safety Evaluation at Bristol-Myers Squibb. She received her PhD in Pharmacology and Toxicology from Duke University in Durham, North Carolina. Kristina joined the pharmaceutical industry at Targeted Genetics then Roche Palo Alto before joining Bristol-Myers Squibb in 2005. During her tenure she's supported IND/CTAs, global marketing applications (NDA/MAA), life-cycle management activities, and has authored numerous peer-reviewed publications. Kristina is a Full Member of the Society of Toxicology (SOT), American College of Toxicology and is a Diplomate of the American Board of Toxicology. She is an active member of SOT, previously serving on the Membership Committee 2016-2019 (Co-Chair 2017-18, Chair 2018-19), the Executive Council of the Women in Toxicology Special Interest Group (Secretary-Treasurer 2002-04, Councilor, 2007-2009, Presidential chair 2010-2014) and as Co-Chair of SOT's Special Interest Group Collaboration Group (2010-2014, Co-Chair 2012-2014).

**Angelique P.J.M. Braen-van Birgelen, Ph.D., DABT, Councilor**

Dr. Braen-van Birgelen is a Sr. Director of Toxicology at Insmed in Bridgewater, NJ. She received her Ph.D. in the field of toxicology from Utrecht University, The Netherlands (1994) and her M.Sc. in human nutrition from The University of Wageningen, The Netherlands (1990). She moved to the US as a Post-Doctoral trainee at the US EPA in 1994 and she is a Diplomate of the American Board of Toxicology since 1999. Dr. Braen-van Birgelen has 20 years of experience in drug development of small molecules, biologics, and devices as a project toxicologist at Hoffmann-La Roche, Ikaria, Bellerophon Therapeutics, and Insmed. She has authored and co-authored over 25 peer-reviewed manuscripts. Dr. Braen-van Birgelen has been a member of SOT since 1997 and has served RSESS as a member

(2018) and Co-Chair (2019) of the program review committee and looks forward chairing the committee in 2020. Within SOT, she is also a member of the awards committee of Women in Toxicology (WIT) and served as Past President (2007), President (2006), Vice-President (2005), President Elect (2004), and member of the Program Committee (2000-2005) of the Mid-Atlantic Chapter of the Society of Toxicology (MASOT). Dr. Braen-van Birgelen is also a member of the American College of Toxicology and served as a Council Member (2010-2012), Chair of the Membership Committee (2011-2012), member of the Program Committee (2013-2014), and member of the Webinar Committee (2012-2018). She is a member of the Association of Inhalation Toxicology and serves currently on the program committee.

**Congratulations to Our 2020 Award Winners!**



**Graduate Student Excellence Award**

Jennifer Schaefer  
Rutgers University



**Graduate Student Excellence Award**

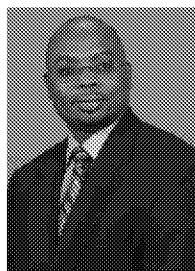
Luma Melo  
Indiana University



**Postdoctoral Fellow  
Excellence Award**  
Colette N. Miller, PhD



**Postdoctoral Fellow  
Excellence Award**  
Katelyn Lavrich, PhD



Patricia  
McGinnis  
(not  
pictured)



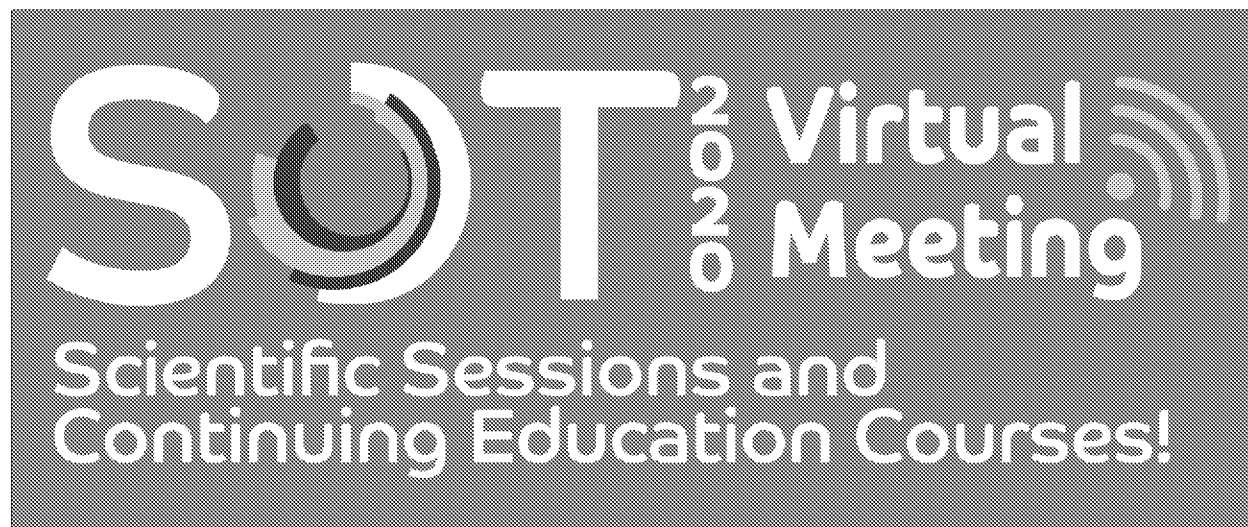
**Best Paper**

*"Data derived extrapolation factors for developmental toxicity: A preliminary research case study with perfluorooctanoate (PFOA)"*

Michael Dourson, Bernard Gadagbui, Chijioke Onyema, Patricia McGinnis, Ray York

## 2020 SOT Virtual Annual Meeting Important Dates!

Over the coming months, SOT will be presenting Scientific Sessions and Continuing Education courses as live webinars. Schedules and registration information will be posted to the Annual Meeting [“Program” page](#) as webinars are confirmed.



## Outstanding Contribution to Regulatory and Safety Evaluation Award to Initiate in 2021

Starting in 2021, the Regulatory and Safety Evaluation Specialty Section (RSESS) would like to recognize an individual who has made significant contributions in areas of regulatory and safety evaluation.

Any RSESS member can nominate an individual for this award by December 1. The nomination should include a summary of key contributions in the regulatory and safety evaluation and include, but not limited to:

- Advancement or enhancement of safety evaluation.
- Development of regulation/guidance documents in safety assessment.
- Extensive contribution in regulatory and safety field.
- Major influence in the education/training/mentorship of young scientists in government, industry, and/or academia.
- Leadership and service to the field including involvement in the RSESS or other organizations related to the regulatory and safety assessment.

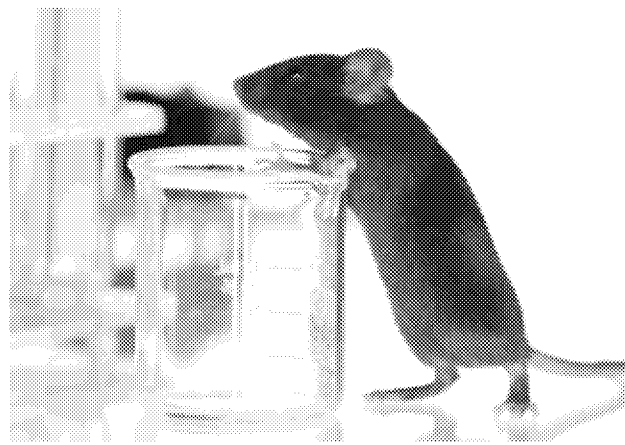
The nomination and the cv of the nominee should be submitted to the Regulatory and Safety Evaluation Specialty Section at the following email address: [RSESSAWARDS@GMAIL.COM](mailto:RSESSAWARDS@GMAIL.COM)

The Awardee will be selected based on the nomination of candidates by the RSESS Awards Committee and RSESS Executive Council. The awardee will be contacted at the end of January, and an engraved plaque will be presented to the awardee and recognized

## Hot Topics Read: US EPA 2035 Animal Testing Phase Out

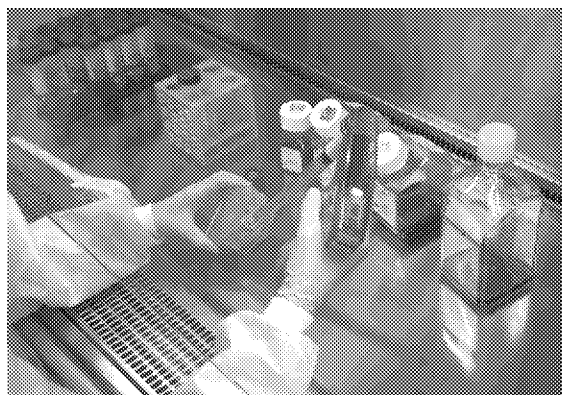
Samantha Goodman, BS

September 9<sup>th</sup>, 2019 marked a groundbreaking day in the field of scientific research. United States Environmental Protection Agency (EPA) Administrator Andrew Wheeler announced a \$4.25 million funding initiative given to five universities to develop "alternative testing methods and strategies that reduce, refine, and/or replace vertebrate animal testing." This was accompanied by an aggressive stance against mammal study requests, promising to reduce agency support by 30% in 2025 with complete withdrawal by 2035.



The U.S. Society of Toxicology encouraged the EPA to remain "flexible" with worry the timeline is unattainable. This new promotion of non-animal-based research comes during a time when toxicologists pursue "the perfect system" to determine toxicological levels in an environment, battling ever increasing chemical presence along with high population indifference to health risks.

However, even the human is not a perfect system for human testing. As stated by Dr. David Threadgill, distinguished professor at Texas A&M University cited for establishment of the Collaborative Cross mouse and known for extensive research within the field of ToxicoGenetics, "All researchers are interested in reducing the number of animals used in research. However, there is scant evidence that non-animal research is more accurate.



Furthermore, the current technologies are not robust to model multi-organ effects. Research into non-animal technologies is important, but animal research still has a critical role in safety evaluation." Total elimination must be based upon ensured animal testing alternatives that do not decrease efficiency or potency of human health defense measures while still holding industrial players accountable.

## Trainee Corner: Toxicology in Action

Samantha Goodman, BS

The Society of Toxicology holds the memberships of hundreds of doctoral students and candidates within toxicological programs across the nation. These programs foster innovative and impactful research studies and professional endeavors from their trainees. The "Trainees in Action" column addition to the RSESS Newsletter hopes to showcase these accomplishments, awards, and unique experiences of trainees throughout the year.

Tox at Texas  
A&M



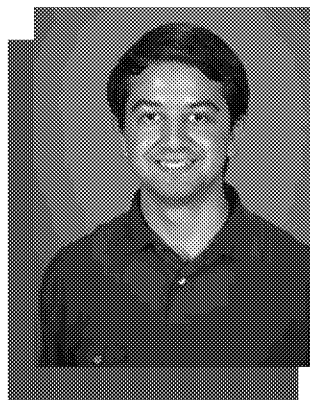
The Texas A&M Interdisciplinary Toxicology Program allows doctoral students to attend a 6-12-week summer externship experience. This alternative program opportunity allows students to experience toxicology in a setting of their choosing, to gain workplace experience and expand their professional communities. Summer 2019 Externship students highlight their personal experience and how it shaped their proceeding graduate experience.

**Alina Roman-Hubers** completed an internship at Chevron in Houston, TX. She was assigned the role of an industrial toxicologist to the Health Team in the Health Environment & Safety Unit. She evaluated different methods of hazard prediction for new substances and products, data gathering for sound science decision-making for new and proposed regulation, and literature reviews for problem solving situations.



Noor Aly received toxicology training at Shell in Houston, TX with the Toxicology Group of the Human Health Risk and Safety Department. She created a tutorial on how to navigate EPA's ToxCast Dashboard and a document containing information about endpoints for chemicals which Shell produces. These decisions about these chemicals regarding their document was designed to assist Shell in making production, distribution and use.

**Alan Valdiviezo** interned at the Texas Commission on Environmental Quality (TCEQ) in Austin, TX. Within the Toxicology division, he worked with a highly skilled and diverse group of toxicologists learning the role of the TCEQ in protecting the residents of the state of Texas. His projects included literature reviews, establishing a database, and even helping to draft an annual air monitoring report.



Have a graduate program or student you would like to have showcased?  
Please email Samantha Goodman at [sgoodman@cvm.tamu.edu](mailto:sgoodman@cvm.tamu.edu).